

POUCH FOR MEDICAL USE

This application claims the benefit of U.S. Provisional Application No. 60/452,585, filed 6 March, 2003 and  
5 Provisional Application No. 60/412,951, filed 23 September, 2002 and is hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

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The present invention relates to a pouch for medical use. The term "medical" may include personal hygiene. In one form, the pouch may be a collection pouch (such as an ostomy pouch) for collecting body fluids. One aspect of  
15 the invention may relate to a medical pouch including separable inner and outer pouches. Another aspect of the invention may relate to a reclosable medical pouch.

BACKGROUND TO THE INVENTION

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Two pouch systems (including an inner and an outer pouch) have been suggested as an alternative to a single pouch ostomy system. However, there remains a need for a pouch design that can combine any of convenience of use, ease  
25 of disposal, ergonomic design and security and assurance against leaks, for good customer acceptance. There also remains a need for a reclosable pouch system for medical use, that can combine any of convenience of use, ease of use, ergonomic design, security and assurance against  
30 leaks.

SUMMARY OF THE INVENTION

In a broad aspect, the invention may provide a pouch for  
5 medical use.

The pouch may include separable inner and outer pouches.

The invention may additionally include one or more of the  
10 following non-limiting features, although additional or  
alternative features will be apparent to the skilled man  
on reading the description of preferred embodiments:

(a)(i) The inner pouch may be fastenable to the outer  
15 pouch or to a body fitment. Such a body  
fitment may support the outer pouch.

(a)(ii) The inner pouch may be fastenable by means of  
20 an adhesive coupling. The adhesive coupling  
may include an adhesive member and a non-  
adhesive member. The or an adhesive member may  
be mounted on the inner pouch and/or on the  
outer pouch/body fitment. The adhesive may be  
a peelable resealable adhesive.

25 a(iii) The inner and outer pouches may have apertures  
which are generally aligned when the inner  
pouch is in an operative position within the  
outer pouch, at least to permit communication  
30 between the interior of the inner pouch, and  
the aperture of the outer pouch.

(b)(i) The inner pouch may be made of a material that  
is disintegratable or dispersible, for example,

to facilitate disposal of the inner pouch in a flushable toilet.

- (b) (ii) The material may be activatable to disintegrate or disperse by addition of an activating agent.  
5 The activating agent may be applied directly to the surface of the inner pouch or it may be added to the toilet water. The activating agent may be a pH-modifier and/or a solvent.
- 10 (b) (iii) The pouch material may include an interior facing water resistant layer and an exterior facing water disintegratable/dispersible layer.
- (c) (i) The pouch (or at least one of the pouches if  
15 more than one pouch is present) may have a reclosable opening.
- (c) (ii) The pouch (or at least one of the pouches if  
20 more than one pouch is present) may include an opening and a sliding zipper for closing the opening. The opening may be at the seam of the pouch. The sliding zipper may comprise a slider having a characteristic to match, or  
25 accommodate, a curvature of the pouch (or a path along which the slider moves). The characteristic may be a degree of curvature of one or more guide surfaces or track-engaging surfaces of the slider. Such a characteristic may enable the slider to move smoothly around a  
30 non-linear path.
- (c) (iii) In the case of a pouch comprising separable inner and outer pouches, the outer pouch may be  
35 openable to provide access for removing and/or fitting the inner pouch.

(c) (iv) A wall of the pouch (or at least one of the pouches if more than one pouch is present) may entirely or partly openable. An openable window portion may be defined in the wall, or an aperture may be openable in the wall, or the wall may be openable at its seam.

(d) (i) The medical pouch may be a collection pouch for collecting body waste. The collection pouch may be an ostomy pouch. The term "ostomy" may include any or all of colostomy, ileostomy and urostomy.

Other non-limiting features and advantages of the invention may include providing a pouch design that may meet one or more of the following, generally conflicting requirements: ease of use, ease of disposal of a waste-containing inner pouch; security and assurance against pouch leakage; and/or ease of manufacture.

Further non-limiting features of the invention will be apparent from the following description of preferred embodiments.

#### DESCRIPTION OF THE DRAWINGS

Non-limiting preferred embodiments of the invention are now described, by way of example, only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic section through a first pouch embodiment;

Fig. 2 is a schematic section similar to Fig. 1, but showing the outer pouch in an opened condition;

Fig. 3 is a schematic section through a second pouch  
5 embodiment;

Fig. 4 is a schematic section through a third pouch embodiment;

10 Fig. 5 is a schematic section through a zipper of the third embodiment;

Fig. 6 is a schematic section along the line VI-VI of Fig. 5;

15 Fig. 7 is a schematic section along the line VII-VII of Fig. 5;

Fig. 8 is a schematic view showing the outer pouch opened, and the inner pouch just prior to insertion in the outer pouch/just following removal from the outer pouch;

20 Fig. 9 is a schematic view similar to Fig. 8, with the outer pouch open, but showing the inner pouch fastened to the outer pouch; and

Figs. 10 is a schematic view similar to Fig. 9, but showing the outer pouch closed.

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#### **DESCRIPTION OF PREFERRED EMBODIMENTS**

The preferred embodiments present various examples of a pouch for medical use. In one form, the pouch is a  
35 collection pouch in the form of an ostomy pouch. The

preferred embodiments illustrate a multi-pouch system. However, it will be appreciated that principles of the invention may be equally applied to a single pouch for medical use. Corresponding reference numerals may  
5 denote corresponding features, where appropriate.

Referring to Fig. 1, an ostomy pouch 10 generally comprises an inner pouch 12 and an outer pouch 14. The inner pouch 12 may include a front wall 16 and a rear  
10 wall 18 secured together around their mutual periphery. The outer pouch 14 may include a front wall 20 and a rear wall 22 secured together around their mutual periphery. For each pouch 12 and 14, the front and rear walls may be formed of separate sheets secured together, or they may  
15 be formed from a common sheet folded at a periphery of the respective pouch 12 or 14.

The outer pouch 14 may include, in its rear wall 22, a first waste inlet aperture 24. An adhesive body fitment  
20 26 may be coupled, fixedly or removably, to the outer pouch 14 around the stoma aperture 24. The body fitment 26 may include a wafer or pad of a skin-friendly adhesive for securing the ostomy pouch 10 to the peristomal region of a wearer. For example, the adhesive may be a  
25 hydrocolloid adhesive. In this embodiment, the body fitment 26 is fixedly secured to the rear wall 22 of the outer pouch 14, for example, by welding, heat sealing or adhesive, to be integral with the outer pouch 14.

30 The inner pouch 12 may include, in its rear wall 18, a second waste inlet aperture 28. The second waste inlet aperture 28 may be slightly bigger than the first waste inlet aperture 24. A first fastener 30, 32 may be provided for fastening the inner pouch 12 to the outer  
35 pouch 14 or to the body fitment 26. In the fastened

position (not shown), the first and second inlet apertures 24 and 26 may be at least partly, or substantially, aligned to provide communication between an interior of the inner pouch 12, and the first inlet aperture. Body waste entering the pouch 10 passes directly into the inner pouch 12. The first fastener 30, 32 preferably provides a substantially liquid-tight and/or gas-tight seal, to prevent waste matter from escaping into the outer pouch 14.

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The first fastener 30, 32 may be a releasable or separable fastener, to enable the inner pouch 12 to be separated from the outer pouch 14/body fitment 26. The first fastener 30, 32 may be a mechanical fastener, or an adhesive fastener. Generally, the first fastener may include a first coupling member 30 surrounding or bordering the second waste inlet aperture, for cooperating (mechanically or adhesively) with a second coupling member 32 carried by the outer pouch 14 or the body fitment 26. The coupling members 30 and 32 may be flat or plate-like, or they may have mechanical engagement profiles.

In this embodiment, an adhesive fastener may be preferred. For example, the first coupling member 30 may be an adhesive faceplate member 30 bordering or surrounding the second waste inlet aperture 28. The second coupling member 32 may be a non-adhesive receiving surface (or "landing" surface) 32 to which the adhesive member 30 may be attached. The adhesive may be of a tacky or non-tacky type. A suitable material for the adhesive member 30 may be a resealable foam tape, such as the type manufactured by 3M company of Minneapolis, Minnesota, and designated 9776 Foam Medical Tape on Liner. The resealable foam tape 30 may include a closed cell

polyethylene foam backing approximately 0.8 mm thick with a hypoallergenic pressure sensitive acrylate adhesive that faces towards the landing surface 32. Another suitable material is a sheet substrate with pressure sensitive adhesive instead of a foam. In either case, the adhesive may initially be protected by a silicone release paper (not shown) prior to first use of the pouch. The landing surface 32 may be provide by a flexible film of plastics, for example, thermoplastics.

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Referring to both Figs. 1 and 2, a wall, for example, the front wall 20, of the outer pouch 14 may be partly, or substantially entirely, openable to provide access for fitting or removing the inner pouch 12. In this embodiment, an openable portion 34 of the front wall 20 may be provided, in the form of a door, flap or hatch portion, to define an access window 35 in the front wall 20. The access window 35 may be of approximately the same size as the inner pouch 12, or it may be larger or smaller than the inner pouch. Generally, a larger size may aid easier insertion and removal of the inner pouch 12. However, the inner pouch 12 is flexible, and may be quite easily inserted or removed through a smaller-size access window 35. The access window 35 may be larger than the outer periphery of the first coupling member 30 of the inner pouch 12.

A second fastener 36 may be provided for fastening closed the openable portion 34. The second fastener 36 preferably provides a liquid-tight and/or gas-tight seal. The second fastener 34 may extend around, or border, a periphery of the openable portion 34 and/or the corresponding confronting edge of the access window 35 in the front wall 20. The second fastener 34 may, for example, be a zip fastener, a sliding zip fastener, a hook-loop fastener (e.g., Velcro <sup>™</sup>), a hook-hook (e.g.,



male-male interlocking) fastener, or a repositionable adhesive fastener (similar to that described for the first fastener 30, 32), or a magnet fastener.

- 5 A deodorising filter 38 may be fitted to one or both of the inner pouch 12 and the outer pouch 14 for deodorising vented flatus. The deodorising filter 38 may be fitted to an interior facing surface of the respective pouch (as in the drawings), or to an exterior facing surface of the  
10 respective pouch 12, 14. The deodorising filter 38 may be fitted to communicate with a gas vent aperture (not shown) in the respective pouch wall.

- Referring to Fig. 2, in use, in order to insert the inner  
15 pouch 12 into the outer pouch 14, the second fastener 36 is unfastened to release the openable portion 34 of the front wall 20. The inner pouch 12 may then be inserted through the open access window 35 in the front wall 20, and pressed into fastening engagement with, for example,  
20 the body fitment 26. In the case of the adhesive member 30 described above, the adhesive member 30 is pressed into adhesive engagement with the landing surface 32 of the body-fitment 26. Thereafter, the openable portion 34 is closed and the second fastener 36 is refastened (Fig.  
25 1).

- Referring again to Fig. 2, in order to remove the inner pouch 12, for example when the inner pouch 12 has become full, the second fastener 36 is unfastened to release the  
30 openable portion 34 of the front wall 20. The ostomate may then fold back a portion of the inner pouch 12 (not shown), to gain access to the first fastener 30, 32. For example, by folding down the upper portion of the inner pouch, the ostomate may gain access to the upper edge of  
35 the first fastener 30, 32. The inner pouch 12 may then

be separated from the body fitment 26, for example, by peeling the first coupling member 30 free of the second coupling member 32. As can be seen in both Figs. 1 and 2, the second coupling member 32 may be larger than the  
5 first coupling member 30 (or may include one or more extension tabs) to provide a gripping surface or portion 40 that the ostomate can grip to counterbalance the peeling forces, and to at least partly isolate the peeling forces from the body fitment 26. Once the inner  
10 pouch 12 has been separated, the inner pouch 12 can be withdrawn from the outer pouch 14 through the access window 35.

The inner pouch 12 may be inserted and/or removed while  
15 the outer pouch 14 is being worn on the body. Alternatively, the inner pouch 12 may be inserted and/or removed while the outer pouch 14 is not being worn.

The inner pouch 12 may be intended to be disposed of in a  
20 flushable toilet. The inner pouch may be of material that is able to withstand body waste and/or other wet contents during normal usage, but is able to disintegrate or at least soften to facilitate disposal in a flushable toilet. The material may be "activateable" by addition  
25 of an activating agent to the toilet water, or to the interior or exterior of the inner pouch 12. For example, the additive may be in the form of a tablet, or powder, or liquid that may be added to the toilet water. Alternatively, the additive may be in the form of a  
30 liquid, an aerosol, or cream that can be sprayed or distributed onto the surface of the inner pouch 12 using a spray or other applicator.

In one example, the inner pouch 12 may be made partly, or  
35 entirely, of a pH-sensitive polymer that becomes soluble

or dispersible in either or both of acid or alkaline conditions (for example, pH below about 4 and/or pH greater than about 10). The activating agent may be an acid or alkaline additive. Example alkaline compounds  
5 may include common base chemicals, such as sodium carbonate, sodium metasilicate, sodium hydroxide, trisodium phosphate, metal mixture compounds, etc.

Another means to soften a polymer material of the inner  
10 pouch 12 is to use an organic solvent as the activating agent. For example, the polymer material may be a pH-sensitive polymer. At least some pH-sensitive polymers may be based on acrylic acid or acrylate, and may be dissolved in certain solvents relatively quickly, such as  
15 acetone, isopropyl alcohol, amino propanol, ethanol amine, etc.

Another possibility may be for the inner pouch 12 to be made partly, or entirely, of a biodegradable polymer that  
20 is water resistant (to withstand the waste contents). The pouch material may be "activated", for example, by spraying a chemical onto the inner pouch 12, to activate the disintegration for the pouch to become flushable or dispersible in a toilet.

25 Another possibility may be for the inner pouch 12 to be made partly, or entirely, of a laminate including a water-soluble or water-dispersible polymer as a bulk layer, and a thin layer of a water-resistant coating  
30 applied to a surface. For example, the water-resistant coating may be applied to the interior facing surface of the inner pouch 12, in order to prevent, or at least obstruct, moisture from the collected waste from damaging the integrity of the material. The exterior surface of  
35 the inner pouch 12 may, in normal use of the inner pouch,

be protected by the outer pouch 14. However, when the inner pouch 12 is removed from the outer pouch 14 and placed in a toilet, the bulk layer of the laminate may be exposed to the toilet water, and may disintegrate or  
5 disperse relatively quickly. The remaining water-resistant coating of the inner pouch 12 may break down physically, as the layer may be too thin to support the weight of the body waste content, or to withstand water agitation during flushing. This technique may not  
10 involve any activation agent to activate the material.

Another possibility is a V-shape pouch, with or without the use of a carrier sleeve, such that the pouch can flow in streamlined fashion through the passages of a toilet  
15 and any sewer or septic line connected to the toilets.

The inner pouch 12 may be made of, or include, a barrier material to prevent odours from transpiring through the material of the pouch wall 12. If a deodorising filter  
20 38 is provided on the inner pouch 12, then the deodorising filter may be sufficiently small that it can be flushed easily in a toilet system without causing blockage. A deodorising filter 38 may be used on the inner pouch 12 even when the inner pouch 12 is not made  
25 of, or does not include, a barrier material. A deodorising agent may also or alternatively be coated onto the material of the inner pouch 12 to deodorise any flatus transpiring through the wall material of the inner pouch 12.

30 The first coupling member 30 may be removable from the inner pouch 12 prior to disposal, or may itself be made of a material that disintegrates or disperses in the toilet, or may be configured (e.g. sufficiently small)

that it does not significantly obstruct flushing and/or can itself be flushed away easily.

5 The outer pouch 14 may be intended to be used multiple times with replacement inner pouches 12. For each replacement of the inner pouch 12, the outer pouch 14 may remain worn on the body or may be removed and then re-fitted to the body. The outer pouch 14 may be configured to provide protection for the inner pouch 12. The inner  
10 pouch 12 may be more fragile than the outer pouch 14 to facilitate at least partial disintegration of the inner pouch 12 in a toilet. The outer pouch 14 may also provide additional security to collect any waste matter that may accidentally escape or leak from the inner pouch  
15 12.

The outer pouch 14 may made of one or more conventional pouch materials not optimised for disposal in a flushable toilet. The outer pouch 14 may be made of a coextruded  
20 film containing heat sealable material as outer skins, and an odour barrier material in between. For example, the heat sealable material may be Polyethylene (PE), or polypropylene (PP), polybutene (PB), or ethylene vinyl acetate (EVA), or ethylene methyl acrylate acetate (EMA),  
25 or ethylene acrylic acid (EAA), etc. The odour barrier material may, for example, be polyvinylidene chloride (PVDC), or ethylene vinyl alcohol (EVOH), or nylons, etc. An example film for the outer pouch 14 may be MF Film <sup>TM</sup> made by Sealed Air Cryovac, or Saranex Film <sup>TM</sup> made by Dow  
30 Chemicals.

The front wall 20 and/or rear wall 22 of the outer pouch 14 may also include a comfort layer on the exterior surface, to provide a soft, comfortable cloth-like

surface. The comfort layer may, for example, be of a non-woven material.

Fig. 3 illustrates a second embodiment very similar to the first embodiment. The main difference in the second embodiment is that positions of the first and second coupling members 30 and 32 are swapped. The first coupling member (e.g., adhesive member) 30 is mounted on the body fitment 26, and the second coupling member (e.g., landing surface) 32 is mounted on the inner pouch 12. Arranging the first and second coupling members 30 and 32 in this way may avoid disposal of the adhesive member 30 in the toilet. Instead, the landing surface 32 may be intended for disposal in the toilet as part of the inner pouch 12. The landing surface may be made of the same activatable and/or disintegratable and/or dispersible material as the inner pouch 12. The example resealable adhesive referred to in the first embodiment may permit repeated adhesion of the same adhesive member 30, thereby allowing multiple replacement inner pouches 12 to be adhered, in turn, to the same outer pouch 14 and body fitment 26.

Figs. 4-10 illustrate a third embodiment very similar to the first embodiment. The main difference in the third embodiment is that the second fastener 36 is integrated in the seam joining the front wall 20 and rear wall 22 of the outer pouch 14. The openable portion 34 of the front wall 20 may therefore be the entire width of the outer pouch 14, providing a wide access window 35. A fixed seam of the outer pouch 14 therefore may not extend around the entire periphery of the outer pouch 14. Instead the second fastener 36 may extend partly or entirely around the periphery. The second fastener 36 may be any of the fastener types referred to in the first

embodiment, but a sliding zipper is preferred and is now described further.

Referring to Figs. 5-7, a first zipper track 50 may be  
5 attached to one of the front and rear walls 20, 22 of the  
outer pouch 14 in Fig 4 (alternatively, the attachment  
may be to 20, 34 in the embodiments of Figs. 1 - 3 as the  
flap opening is on the face instead of the seam), and a  
second zipper track 52 may be attached to the other of  
10 the front and rear walls 20, 22 of the outer pouch 14 in  
Fig. 4. The first and second zipper tracks 50, 52 may be  
male and female tracks, respectively. The zipper tracks  
50 52 may be generally curved to match the curved  
peripheral shape of the outer pouch 14 (for example, as  
15 seen in Figs. 8-10). A zipper slider 54 may be captive  
on the tracks 50 and 52 for fastening and unfastening the  
zip tracks 50, 52. The slider 54 may be generally  
channel shaped, and include a bridge 56 and two depending  
side walls 58 defining a channel region 60. The side  
20 walls 58 of the slider 54 may carry guides 62 that engage  
behind the tracks 50, 52 to hold the slider 54 captive on  
the tracks. The channel region 60 may be narrower at one  
end 54a (e.g. the right as seen in Fig. 5) of the slider  
54 than the other end 54b. Moving the slider 54, for  
25 example, leftwards fastens the zip by pressing the male  
and female tracks 50, 52 into mutual engagement with each  
other. A pressing projection 64 located near the end 54a  
of the slider 54 may aid application of pressure to urge  
the tracks 50, 52 together. Moving the slider 54, for  
30 example, rightwards unfastens the zip by separating the  
male and female tracks 50, 52. Separation may be aided  
by a separation projection (blade) 66 depending from the  
bridge 56 and/or by a difference in the height of the  
guides 62 at the end 54b of the slider to promote lifting  
35 of one track relative to the other.

As best seen in Fig. 5, the slider 54 may have a curved characteristic that matches and/or accommodates the curved shape of the zipper tracks 50, 52. The curved  
5 characteristic may define a curvature that is not significantly smaller (e.g., radius of curvature is not significantly greater) than the maximum curvature (e.g., minimum radius of curvature) of the periphery of the outer pouch 14 over which the zip extends. For example,  
10 the curved characteristic may be an interior surface 56a of the bridge 56, which has a curvature that is not significantly smaller than the maximum curvature of upper periphery of the pouch. (The bridge surface 56a may be shaped to have a radius of curvature that is not  
15 significantly greater than the minimum radius of curvature of the upper periphery of the pouch). The bridge 56 may act as a guide for guiding movement of the slider 54 relative to the tracks 50, 52. Additionally or alternatively, the curved characteristic may be defined  
20 by surfaces 62a of the guides 62 that confront the zipper tracks 50, 52. The guide surfaces 62a may be inclined or curved along an arc 68 having a curvature that is not significantly smaller than the maximum curvature of the upper periphery of the pouch. (The arc 68 may have a  
25 radius of curvature that is not significantly greater than the minimum radius of curvature of the upper periphery of the pouch).

Such a curved characteristic may enable the slider 54 to  
30 slide smoothly around the curved shape of the outer pouch 14. This may be especially advantageous for the elderly or less dextrous, or for ostomates with sensitive stomas who wish to avoid discomfort as the slider 54 is operated.

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Referring to Figs. 8-10, the second fastener (zipper) 36 may extend for a half, or more, of the periphery of the outer pouch 14. In the form illustrated, the length of the zipper 36 may be about two-thirds, or more, of the periphery. Such a length of zipper 36 allows the inner pouch 12 easily to be inserted in, or removed from, the outer pouch 14, and it may also provide substantially unhindered access to the first fastener (30, 32) for removably securing the inner pouch 12 in position.

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The zipper 36 may be arranged to open an upper portion of the outer pouch 14. Opening an upper portion may be advantageous in providing access to the stoma aperture. A lower portion of the outer pouch 14 may have a permanently sealed seam 70. The permanently sealed seam 70 may act as a failsafe to ensure that the inner pouch 12 cannot accidentally drop downwardly out of the outer pouch 14.

20 The zipper may be made of any suitable material, such as metal or plastics or fabrics.

The invention, particularly as described in the preferred embodiments, can provide a pouch design that may meet multiple, generally conflicting requirements, in terms of ease of use, ease of disposal of a waste-containing inner pouch, security and assurance of the wearer against pouch leakage, and ease of manufacture.

30 The foregoing description is merely illustrative of preferred forms of the invention, and does not limit the invention. The skilled man will appreciate that many alternatives may be used within the principles and/or scope of the invention.

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